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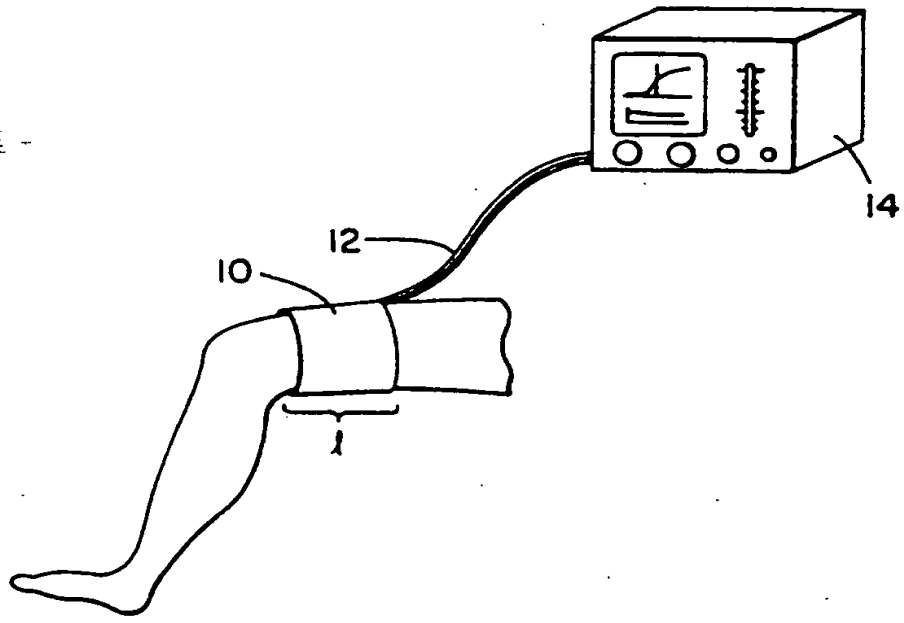
(54) Peripheral arterial monitoring instruments.

(57) An apparatus for determining peripheral arterial capacity and compliance comprises a blood pressure cuff (10) which is inflated and deflated around a limb of the body in order to take pressure measurements. The volume of air removed from the cuff is determined in a quantifiable manner, for example by expelling air through an orifice of known characteristics. The detected pressures and volume of air removed are used to compute oscillation volume, which in turn is used to display arterial capacity and compliance as a function of transmural pressure and time. Arterial capacity may be displayed in terms of arterial radius, arterial cross-sectional area, or arterial volume. Also, systolic and pulse pressures are determined using only these determined values.

FIG. 1



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Field of the Invention

This application is a continuation-in-part of Serial No. 823,909, which is a continuation of Serial No. 453,519 now U.S. Patent No. 5,103,833, both of which are incorporated herein by reference.

This invention relates to monitoring instruments which provide information concerning peripheral vasculature and, in particular, to the use of such instruments to provide medical diagnostic information concerning arterial volume, cross-sectional area, and compliance, and especially, diastolic and systolic pressure.

Background of the Invention

The medical conditions of arteriosclerosis and hypertension are potentially debilitating and often life-threatening conditions which require early diagnosis and treatment. These conditions are characterized by changes in arterial blood flow volumes and rates and the response of arterial tissue to changes in blood pressure. A physiological phenomenon which plays a part in these arterial characteristics is referred to herein as arterial compliance, the ability of vasculature to respond to changes in these conditions. The arterial walls of the body include collagen, giving the walls the ability to expand and contract, and muscle tissue which in part controls this expansion and contraction. Vascular compliance includes the response of collagen and muscle in arterial walls to changing conditions. In addition, the condition of arteriosclerosis is characterized by the buildup of fatty substances along arterial walls. These substances can occlude the artery, and can impede the ability of the arterial walls to respond to changing conditions of blood pressure. The fatty substances characteristic of arteriosclerosis are thus a further factor governing arterial compliance. It is thus desirable to be able to analytically understand arterial volume and compliance when diagnosing or treating the medical conditions of hypertension and arteriosclerosis.

An understanding of a patient's arterial volume and compliance is also beneficial when administering anesthesia. The quantity of anesthetic administered to a patient should be just sufficient to eliminate a physiological response by the patient during surgery. If an insufficient amount of anesthetic has been administered, the cardiovascular system will respond reflexively when the patient is intubated prior to surgery. This response can be detected by monitoring arterial volume and compliance, and noting any reduction in these characteristics during intubation. A cardiovascular response can also be detected at the time of the first surgical incision, when an insufficient anesthetic will again be evidenced by a reduction in arterial compliance or volume. Thus, a surgical patient would benefit from the monitoring of arterial volume and compliance by the anesthesiologist and surgeon.

The significance of arterial volume and compliance has been recognized in the prior art. In a sequence of patents including U.S. Patents 3,903,872; 4,565,020; 4,651,747; and 4,712,563 issued to William T. Link, methods and apparatus are described for calculating measurements of arterial volume and compliance. Link's technique as described in these patents involves taking and using a series of standard oscillometric blood pressure measurements. The first time derivative of the measured cuff pressure pulse, dP, at a time within a patient's actual blood pressure pulse as a function of applied cuff pressure is then calculated to inferentially determine arterial volumetric changes dV. As Link shows, this first derivative corresponds to changes in arterial volume changes dV. A curve plotted from these calculations is transformed by Link to a curve of volumetric change as a function of transmural pressure, V/P, and this curve may in turn be differentiated to obtain a compliance curve dV/dP.

In a second sequence of patents including U.S. Patents 4,664,126; 4,697,596; 4,699,151; and 4,699,152, Link extends this analysis to a technique in which the peak to peak amplitude of each cuff pulse and the patient's diastolic and systolic pressures are used to calculate a particular patient's own volumetric and compliance curves. Again, the volumetric and pressure information is determined inferentially from arterial pressure pulse information. The volumetric and pressure curves are used by Link in the determination of systolic, diastolic, and mean arterial blood pressure. The Link technique utilizes a ramp-up method of measuring pressure pulses, wherein pulse data is taken during inflation of a blood pressure cuff. The currently preferred technique for taking such measurements, which is incrementally deflating a blood pressure cuff from a pressure level in excess of systolic pressure and taking measurements over a range of declining pressure steps, is described in U.S. Patents 4,349,034 and 4,360,029, issued to Maynard Ramsey, III.

A display of information concerning arterial volume which is useful to the anesthesiologist, surgeon or diagnostician is a curve representing arterial volume (in cc) or area (in mm^2) as a function of transmural pressure (in mm Hg). At a given point on the positive pressure side of this curve the volume or area may be represented by a value R, the effective arterial radius. The slope of the curve at any given point, dV/dP, represents arterial compliance, and a plot of dV/dP as a function of transmural pressure represents the arterial compliance curve.

In accordance with the principles of a parent of this invention, Serial No. 453,919, now U.S. Patent No.

5,103,833, the patient's arterial volume and compliance is represented in this format and, in correspondence thereto, the value of R over time is calculated and displayed. The display of this data provides the anesthesiologist with information concerning the patient's arterial volume and compliance characteristics, and also provides information as to changes occurring in arterial volume over time. This will enable the anesthesiologist to detect any response of the cardiovascular system to intubation or incision during a surgical procedure, thereby facilitating the correct delivery of anesthetic to the patient.

A display as described above may be further enhanced by providing the arterial compliance dV/dP at a given transmural pressure for a patient undergoing diagnosis or monitoring. The maximum value of dV/dP, referred to as peak arterial compliance, can also be ascertained from this information. A further display of this information which would be of use to a clinician would be a representation of arterial capacity, R, in relation to the radius of the limb at which the blood pressure cuff of the monitoring instrument is attached.

In accordance with another aspect of the aforementioned patent, a variation of this display format provides a display of the patient's arterial volume data prior to the initiation of any surgical intervention and, in correspondence therewith, a current display of arterial volume data as the surgical intervention proceeds. Comparison of the data informs the anesthesiologist of the cardiovascular system response to bodily stimuli during the procedure.

A recent proposal relating to the determination of vascular compliance is known as the "Hartsafe Product Concept." This product concept is further described in Raines, Jaffrin and Rao, "A Noninvasive Pressure-Pulse Recorder: Development and Rationale", Medical Instrumentation, Vol. 4, Sept. - Oct. 1973, pp. 245-250. In this procedure, a pressure cuff is strapped to a patient's calf and inflated. When the cuff pressure attains a level of 70 mm Hg, a calibration step is initiated by injecting one ml of air into the cuff. The system measures the change in pressure resulting from this quantified injection and calculates a calibration factor based upon the change. Cuff inflation continues and volume pulse signals are recorded until a minimal volume pulse signal or a maximum pressure value of 225 mm Hg is attained. The system then commences a step deflate sequence. At individual pressure decrement steps of 10 mm Hg the volume pulse signal is recorded. The sequence continues until a minimal pressure level is attained, at which time data acquisition is complete. The system then performs "signal conditioning" using the volume pulse and cuff pressure signals at each 10 mm Hg cuff pressure decrement, and the calibrate signal previously stored. The volume-pressure curve, peak compliance, and other parameters are obtained by this "signal conditioning." The Raines/"Hartsafe" approach seems to be a more direct measurement of arterial volume than the Link techniques, in which arterial volume is calculated premised upon its relationship to the arterial pressure pulses, because an actual measurement of system response to a known change in cuff volume is taken during the calibration step of "Hartsafe." But the actual data which is computed for the volume-pressure curve appears to be similarly inferential, however, as the single calibration volume measurement is the only volumetric measure used in conjunction with the pulse signals to inferentially calculate the curve.

It would be desirable to provide arterial volume and compliance information that is based upon direct measurements of arterial volume and changes in arterial volume. It would further be desirable to continually recalibrate the system during the acquisition of such volumetric data, or to obviate the need for calibration entirely by obtaining highly accurate volumetric data in the first instance. In accordance with a further aspect of Apple, U.S. Patent No. 5,103,833, a system for measuring arterial cross-section and compliance is provided in which a pressure cuff on a peripheral part of the body is inflated to a pressure level which occludes arterial vessels. The cuff is then deflated, and pressure measurements taken in correspondence with decreasing pressure levels. Air which is expelled during deflation is removed from the cuff through means for determining the volume of air expelled. This means may comprise, for instance, an orifice or transfer volume of known characteristics, or a flow measurement device. At each point at which a pressure determination is made, the volume of air removed from the cuff is precisely known, or is calculated based upon an immediately obtained volumetric calibration. Thus, there is no need for the use of a calibration factor or reliance upon a single prior calibration step in the determination of arterial volume and compliance performed by the system.

As air is removed from the pressure cuff in accordance with the Apple invention, the oscillation pressure peaks and changes in cuff volume as a function of pressure are recorded over a range of cuff pressures. From this information the oscillation volume is calculated. From the knowledge of oscillation volume measurements over the range of cuff pressures and conventional determination of systolic and diastolic pressure levels, the patient's arterial volume and compliance curves are reconstructed. Thus, accurate and complete information concerning blood pressure and arterial volume, cross-section and compliance in relation to transmural pressure and/or time is provided to the physician for monitoring and diagnosis.

Summary of the Invention

The methods and apparatus described by this invention disclose a means for performing measurements of vital signs which includes only: an inflatable cuff; inflating and deflating means connected to the cuff; means coupled to the inflating and deflating means which expels air from the cuff in decremental amounts, so that it may be quantified; and computational means which use these determined cuff pressures and decremental volumes to determine arterial volume, arterial capacity (compliance), volume versus pressure, and, importantly, diastolic and systolic blood pressures of the patient. Methods are also described for making all the above determinations. Importantly, it should be realized that the methods and apparatus herein described do not require a prior knowledge of the patient's systolic and diastolic pressures. This significant advancement allows it to be possible to construct an actual (and not proportional) pressure-volume curve, to determine parameters such as arterial volume, arterial diameter and arterial compliance at different arterial wall pressures, and to determine better the diastolic and systolic pressures, which are ultimately more accurate than the determinations made using current techniques.

This invention will be better understood when read in connection with the attached Description of the Drawings taken in conjunction with the Detailed Description of the Invention.

Description of the Drawings

In the drawings:

FIGURE 1 illustrates a peripheral arterial monitoring instrument of the present invention attached to the thigh of the body;

FIGURES 2a and 2b illustrate two types of vascular information displays of the instrument of FIGURE 1;

FIGURES 3a and 3b illustrate a peripheral limb of the body in relation to the information displays of FIGURES 2a and 2b;

FIGURE 4 illustrates schematically the connection of a arterial monitoring instrument to a limb of the body;

FIGURE 5 is a schematic illustration of a peripheral arterial monitoring instrument of the present invention which uses an orifice for measured deflation;

FIGURE 6 is a graphical illustration of step deflation using an orifice for calibrated deflation;

FIGURE 7 is a schematic illustration of a peripheral arterial monitoring instrument of the present invention which uses a transfer volume for measured deflation;

FIGURE 8 is a graphical illustration of step deflation using a transfer volume for calibrated deflation;

FIGURE 9 is a graphical representation of flow versus pressure across the deflate orifice;

FIGURE 10 is a graphical representation of oscillation pressure versus cuff pressure;

FIGURE 11 is a graphical representation of volume reconstruction versus cuff pressure;

FIGURE 12 is a graphical representation of estimated values using the method of the present invention of volume versus wall pressure;

FIGURE 13 is a graphical representation of the values of FIGURE 12 after using optimization techniques;

FIGURE 14 is a graphical representation of the estimated values of volume parameters made using methods of the present invention; and

FIGURE 15 is a graphical representation of the values of FIGURE 14 after using optimization techniques.

Detailed Description of the Invention

Referring first to FIGURE 1, a peripheral arterial monitoring instrument constructed in accordance with the principles of the present invention is shown in use on the leg of a patient. The instrument includes a conventional blood pressure cuff 10 having a length ℓ which is wrapped about the thigh of the patient. Although the cuff 10 may be applied to any peripheral part of the body and is most conventionally applied to the upper arm, it is preferable to use the thigh in some procedures as that is where buildups of occlusive substances leading to arteriosclerosis and the like generally first manifest themselves. In other applications the upper arm or finger may be a preferred site for application of the cuff. The cuff 10 is connected by tubing 12 to a monitor and processor 14. The monitor and processor 14 includes a number of controls for actuating and adjusting the instrument in the performance of vascular measurements including blood pressure determination. The monitor and processor also includes a display 16 where the data taken during measurements of arterial volume is displayed, either in numerical or, preferably, in graphical form as shown in FIGURES 2a and 2b. Further, the monitor and processor includes a controlled pneumatic system which controls inflation and deflation of the cuff 10 during which time measurements leading to the determination of the patient's arterial volume and compliance are taken.

FIGURES 2a and 2b illustrate several preferred techniques for displaying the information obtained through these measurements. In the upper portion of the display of FIGURE 2a is a graphical display of arterial volume (or arterial cross-sectional area, or arterial radius) versus transmural pressure. As the arteries in the peripheral body part are infused with blood, the arteries expand and their volume increases as shown by the righthand portion of curve 20. The height of the righthand portion of the curve 20 also represents the effective radius of the arterial vessels R when the vessels are filled with blood. The slope of the curve 20, dV/dP, represents arterial compliance and the point at which dV/dP exhibits a maximum value is generally referred to as peak arterial compliance. Thus, the upper graph of FIGURE 2a provides the physician with information as to arterial volume, compliance and effective arterial radius in the limb where the cuff is affixed.

Below the volume versus pressure graph is a graphical representation of changes in the effective arterial radius over time. This parameter may be monitored by the anesthesiologist to provide information as to bodily responses during surgery. The illustrative curve 22 of R versus time shown in the drawing is seen to be substantially flat, except at time indicated by 23. This decrease in the R value may correlate for instance with the time at which some physical intervention such as intubation or incision is performed on the patient. If the patient is not fully anesthetized at that time, the cardiovascular system will react by contracting the arteries of the body, and the effective radius of arterial vessels will decline. Thus, the decline in curve 22 at point R would indicate to the anesthesiologist that the patient is not fully anesthetized, and further anesthetic may be required for patient comfort and safety.

FIGURE 2b shows a further display of the arterial volume and compliance information which would be of assistance to an anesthesiologist. In this display volume versus pressure information is displayed before the administration of anesthesia. This curve of the patient's normal arterial volume is labelled as V(P) and the initial curve determined by the monitor and processor. As administration of the anesthetic proceeds, the patient's cardiovascular system will respond by contracting or dilating the arterial vessels. A current volume versus pressure curve is calculated periodically and displayed in correspondence with the initial curve. The current curve is labelled V(P) curr. in FIGURE 2b. Thus, the display of FIGURE 2b provides the anesthesiologist with a continuous comparison of current arterial volume and compliance versus the patient's normal arterial volume and compliance prior to the administration of anesthetic.

FIGURES 3a and 3b are cross-sectional illustrations of arteries showing the parameters measured by the monitor and processor 14. The R value is the radius of an artery 30 as shown in FIGURE 3a. Since the cuff encloses all arterial vessels in the portion of the limb about which it is wrapped, it will be understood that the R value is not the radius of a particular artery, but is in effect the sum of the radii of all of the arteries inside the cuff 10. Thus, the instrument provides an R value which is the effective radius taken over all arterial vessels inside the cuff.

The artery 30 is defined by the arterial wall 32. The arterial wall is composed principally of two substances, collagen and smooth muscle tissue. Collagen provides the artery with flexibility, the ability to stretch and deform. This rubber-like characteristic is one contributor to arterial compliance, and is a passive characteristic of arteries. The muscle tissue is controlled by nerves to provide stretching and deformation of the artery under control of the body's nervous system. This stretching and deformation is an active characteristic of the artery which also is a factor in arterial compliance.

Arterial volume and compliance are also affected in the case of arteriosclerosis or hardening of the arteries by the buildup of fatty substances on the inner walls of the arteries. This condition is shown in FIGURE 3b, where a buildup of substances is indicated at 34 lining the wall of the artery. The ability of the artery to expand or contract under the influence of arterial muscular contraction or blood pressure changes is adversely affected by this lining of fatty substances, which can retard such motion. Since the substances also occupy a portion of the inner volume of the artery, the effective radius of the vessel R' is decreased by the presence of these substances.

It may be appreciated that if the R value for an artery or a group of arteries is known, a calculation of the cross-sectional area of the artery at that location can be performed by executing the equation $A = \pi R^2$. From this calculation of arterial area, arterial volume V may be calculated by multiplying the area by P, the effective length of the cuff 10 which encloses the vessels of effective area A. Thus, a measurement of V will yield a value for R, and vice versa.

FIGURE 4 illustrates an arrangement for taking measurements of arterial volume and compliance. Shown in FIGURE 4 are a limb of the body 40 in cross-section, about which a blood pressure cuff 10 is wrapped. The skin line of the limb is indicated at 41. The cross-sectional view of the limb shows the bone 42 at the center of the limb, and an artery 44 passing through the limb. The artery 44 is shown expanded during the pumping of blood, before the cuff is applied and inflated. After inflation of the cuff to a maximal pressure, the artery will be occluded, as shown at 44'.

The cuff 10 is connected by pneumatic tubing to a pump 50. The pump 50 pumps up the cuff 10 at the

start of the measurement cycle. The arrangement of FIGURE 4 is modified to perform the process of the "Hartsafe Product Concept" discussed above by the inclusion of a calibration chamber 54, which is connected to the pneumatic system. As explained above, at the beginning of the inflation cycle the pump 50 is stopped and one ml of air is injected into the pneumatic system of the cuff. This may be accomplished by moving piston 56 in the chamber 54 to the right to displace one ml of air from the chamber. Given that all elements of the pneumatic system are substantially non-compliant, this one ml volume of air will compress the limb 40 by one ml. If all tissue and structure within the limb are assumed to be substantially liquid in nature and hence substantially non-compliant, the effect of the piston displacement will be to displace one ml of blood from the vascular system within the confines of the cuff. By taking pressure measurements before and after this injection of air, the process of the Raines method or the "Hartsafe Product Concept" calculates its calibration factor at the outset of the measurement cycle. The pump then inflates the cuff to fully occlude the arterial vessels as shown at 44', and the deflate cycle commences. During deflation, a deflation valve opens and closes to incrementally bleed air from the pneumatic system. Measurements taken by a pressure transducer P_T at each pressure step are stored in correspondence with cuff pressure level and are subsequently used in a signal conditioning (processing) step at the end of the deflation cycle.

The arrangement of FIGURE 4 is seen to exhibit pneumatic structural, control, and operational complexity due to the inclusion of the calibration chamber 54. Furthermore, the calibration step is performed only once, at the outset of the inflation cycle. FIGURE 5 illustrates a peripheral arterial volume and compliance measurement system of the present invention which obviates the need for such structural and operational complexity. In FIGURE 5, the blood pressure cuff 10 is wrapped around the thigh 60 of the patient, shown in cross-section. The femur 62 is shown in the center of the thigh, and the skin line of the thigh is indicated at 61. The femoral artery is illustrated at 64 in an unoccluded condition, and in an occluded condition at 64'. The cuff 10 is connected by pneumatic tubing 12 to a pump 50, a pressure transducer P_T, and a deflate valve 52. An orifice 66 of predetermined cross-sectional area is located in the deflate valve outlet.

In operation, the pneumatic system of FIGURE 5 is operated in the conventional manner of a step-deflate automated blood pressure monitor such as the Critikon Dinamapç 8100. The cuff 10 is inflated by the pump 50 to a pressure which is in excess of systolic pressure, sufficient to fully occlude the artery 64'. The cuff pressure is stepped down, and the cuff pressures and oscillation pulses are recorded from the pressure transducer. Two of the pressure steps during the deflate cycle are shown in FIGURE 6. The cuff pressures of the two steps are P_1 and P_2, and the oscillation pulses are shown as P_{osc}. The cuff pressure is stepped down in decrements of approximately 8 mm Hg. Since the air removed from the pneumatic system is expelled through an orifice of known size, the volume of air removed between each step can be calculated from a flow equation derived from the gas law PV = nRT, where P is pressure, V is volume, n is Avogadro's constant, R is the gas constant, and T is absolute temperature. Since the pressure on the outlet side of the orifice is ambient atmospheric pressure and the pressure on the deflate valve side of the orifice is the cuff pressure when the deflate valve is open, as measured by the pressure transducer relative to ambient pressure, the gas flow can be calculated from knowledge of the orifice size and the time during which the deflate valve is open. The time during which the deflate valve is open is shown in FIGURE 6 as Δt.

In a constructed embodiment of the present invention the flow of air from the pneumatic system is calculated from the equation

$$FLOW = [(760 + P)/760] \cdot [(e^{\gamma \ln(760/(760+P))}) - (e^{1.71 \ln(760/(760+P))})]^{0.5}$$

where P is the pressure across the orifice, the number 760 is an adjustment factor for nominal barometric pressure, and γ is an adiabatic constant, typically $\delta = 1.4$. The flow through a 1 cm^2 orifice as a function of the pressure across the orifice during a typical deflate cycle is represented graphically in FIGURE 9. Other known methods for measuring the flow of a fluid may also be employed; for instance, if the orifice in a given embodiment does not conform to theoretical models, it may be approximated empirically.

Once the FLOW has been found between each step the volume of air removed during each decrement, ΔV_n, is computed from the equation

$$\Delta V_n = A_{eq} \cdot FLOW_n \cdot \Delta t_n$$

where A_{eq} is the equivalent area of the orifice, $FLOW_n$ is the flow rate between two pressure steps, and Δt_n is the time during which the deflate valve was open between the two pressure steps. The FLOW is known from the preceding equation, the equivalent area of the orifice is known, and the time during which the deflate valve is open is measured by a digital clock which runs during the time that the valve is open. Since the FLOW calculation is done for each deflation step based upon the known orifice and the then extant pressure, no recalibration or modification is necessary or required for the calculated values.

From the foregoing data a ratio can be formed of the ΔV_n values and the respective cuff pressure differentials at which they were obtained. The ratio is of the form

$$\Delta V_n/\Delta P_{(decr\ n)}$$

where ΔP_{decr} is equal to $P_1 - P_2$ for the respective pressure step. From this ratio and the recorded values of P_{osc} the volume oscillations can be calculated from the expression

$$V_{osc\ n} = P_{osc\ n} \cdot \Delta V_n / \Delta P_{decr}$$

for each step decrement. The value of $P_{osc\ n}$ used for each step decrement may be the amplitude of the oscillation pulses on the P_1 step, the P_2 step, or an average of the two, due to the very small variation in oscillation pulse amplitude from one step to the next. Whichever approach is used, it is consistently applied for the full range of step values. Curves representing V_{osc} and the oscillation pulses as a function of cuff pressure are illustrated in FIGURE 10.

Using these volume oscillation values for the deflate cycle the arterial volume curve can now be computed in a two-step procedure. The first step is to compute a curve referred to herein as a reconstruction curve from knowledge of the $V_{osc\ n}$ values and the values of systolic and diastolic blood pressure determined by the Dinamap™ in the conventional manner. The arterial volume curve is then computed by coordinate system transformation, by which the reconstruction curve, referenced to cuff pressure, is converted to arterial transmural pressure with reference to systolic pressure. The equation for computing the reconstruction curve is of the form

$$Recon_n\ (P_{cuff}) = V_{osc\ n}(P_{cuff}) + Recon_n(P_{cuff} + S - D)$$

where S is systolic pressure and D is diastolic pressure and the difference of systolic minus diastolic pressure is referred to herein as pulse pressure. It is known that

$$Recon_n(P_{cuff} + S - D) = 0$$

when $(P_{cuff} + S - D)$ is greater than $P_{cuff\ max}$, where $P_{cuff\ max}$ is the maximum cuff pressure used in a particular measurement. This follows from the knowledge that at maximum cuff pressure the arteries in the limb are completely occluded. The reconstruction curve equation is seen to contain the value $Recon_n$ on both sides of the equation. Hence, the equation is solved recursively for n = 1...N where 1...N are the deflation step levels. A graphical plot of the points $Recon_n(P_{cuff})$ as a function of cuff pressure is shown by the dashed curve Recon in FIGURE 11 in comparison with the V_{osc} curve previously shown in FIGURE 10. It is seen that the plot of Recon converges with the V_{osc} curve above and in the vicinity of systolic pressure.

Using the $Recon_n$ data points, the arterial volume may be calculated as a function of transmural pressure by, in effect, transforming the Recon curve about the axis of systolic pressure. The equation for performing this transformation is of the form

$$P_{transmural} = \text{systolic pressure} - P_{cuff}$$

The arterial volume curve produced by this transformation is of the general shape of curve 20 of FIGURE 2a and the curves of FIGURE 2b.

From the data points used to plot and display the arterial volume curve, the display of FIGURE 2a is readily developed. A point of reference for selection of R and dV/dP may be chosen in a number of ways. The monitor may compute mean arterial pressure in the conventional manner, and use the value of mean arterial pressure as the pressure for which R and dV/dP are chosen and displayed. Alternatively, the pressure at which dV/dP is at a maximum, peak arterial compliance, can be used as the pressure reference for selecting R and dV/dP. As a third alternative, the physician selects a transmural pressure value on the abscissa of the upper curve of FIGURE 2a as the pressure for R and dV/dP. The slope of the curve at the selected pressure point can be calculated to determine arterial compliance dV/dP, and the amplitude of the volume curve at the selected pressure provides the R value.

During a surgical procedure the instrument is repeatedly actuated automatically and an R value is found each time. The R value is then displayed as a function of time as shown at the bottom of FIGURE 2a. Alternatively, the volume curve calculated at the beginning of a surgical procedure is stored and continuously displayed with the most recently calculated curve in the format shown in FIGURE 2b.

Another display which can be obtained from this data which would be of use to a clinician is a plot of dV/dP versus time, showing historic changes in the patient's arterial compliance during a surgical procedure. To gauge the effectiveness of a patient's cardiovascular system, another alternative is to display R (or arterial area or volume) as a function of limb size. Limb size is obtained by measuring the circumference of the limb where the cuff is attached, and entering this information into the monitor and processor 14. The ratio of this R (or arterial area or volume) to circumference (or calculated limb radius or cross-sectional area) provides an indication of cardiovascular efficiency.

Alternative to the orifice of FIGURE 5, a flowmeter which measures the flow of expelled air could be used to provide a direct measurement of flow volume at the output of the deflate valve 52. Another alternative embodiment is to use a transfer volume of known capacity as shown in FIGURES 7 and 8. The transfer volume comprises all of the volumetric space between an intermediate dump valve 52a and the deflate valve 52. The size of the vessel indicated at 58 is chosen to provide the desired volume of the entire transfer volume. To deflate the cuff 10, the deflate valve 52 is closed after previous closure of the dump valve 52a. The air in the transfer volume between the two valves is now at atmospheric pressure. The dump valve 52a is then opened,

and the transfer volume becomes pressurized to the cuff pressure, which declines to P_{tr} by reason of the expansion of pressurized air into the transfer volume. From a knowledge of the previous cuff pressure P_1 and the new cuff pressure P_{tr} as measured by the pressure transducer and the known volume of the transfer volume, V_{tr}, the volume of pressurized air which has been transferred into the transfer volume and removed from the cuff can be readily computed using the gas law

$$\Delta V_{tr} = \Delta V_c = V_{tr}\,[1 - (760/(760 + P_{tr}))^{1/\gamma}]$$

where ΔV_c is the volume of air removed from the cuff at pressure P_{tr} and P_{tr} is in mm Hg. This volume transferred bears a relationship to the pressure decrement which is

$$\Delta V_{tr}/(P_1 - P_{tr})$$

which establishes a factor from which to compute the volume oscillation on a per decrement basis:

$$V_{osc\,n} = [\Delta V_{tr}/(P_1 - P_{tr})]_n \cdot P_{osc\,n}$$

The deflate valve 52 is then opened so that both valves are in the open condition. Air is expelled from the pneumatic system of the cuff and the pressure transducer is monitored until the pressure reaches the level P_2, at which point the dump valve 52a is closed. The deflate valve 52 is then closed, stabilizing the transfer volume at atmospheric pressure in preparation for the next step decrement. The transfer volume technique is advantageously employed to enable use of a total pressure step P_1-P_2 which is conventional for a standard blood pressure monitor such as the Dinamap™ 8100, which uses pressure step decrements of approximately 8 mm Hg. Thus, arterial volume and compliance are obtained during the course of a normal blood pressure measurement taken by a standard automated noninvasive blood pressure monitor.

An improved reconstruction method is now described which has improved noise rejection characteristics and, most importantly, does not require prior knowledge of systolic and diastolic pressure. The starting point is volume oscillations versus cuff pressure as previously described and shown in example form in FIGURES 12 and 13. It has been found that a very simple equation relates to all of the applicable parameters which determine the desired vital signs. This is shown below as Equation 1:

$$VARTEST(P_{art}) = Ao * [1 + (2/\pi) * Arctan(P_{art}/C)] + (Slope * P_{art}) + E \quad (1)$$

where

$VARTEST(P_{art})$	= Estimated arterial volume as a function of arterial wall pressure
P_{art}	= Pressure across the wall
	= $P_{bp} - P_{cuff}$
P_{bp}	= Unknown blood pressure coefficient
Ao	= Unknown area or volume coefficient
C	= Unknown curve shape coefficient
Slope	= Unknown coefficient for $P_{art} \geqq 0$
Slope	= 0 for $P_{art} < 0$
E	= Unknown coefficient for adjustment of occlusial constraint

This equation is an arctangent function with a linear term added for positive arterial pressures. Equation 1 now has four unknown constants; Ao, SLOPE, C, and E. Ao is the arterial volume (or area) at zero transmural pressure. SLOPE is the change in arterial volume with respect to the change in pressure across the wall. In other words, SLOPE estimates arterial compliance at high wall pressures. C is a parameter which describes the shape of the compliance curve, and the elasticity of the artery as it is being occluded. Finally, E is a parameter which adjusts the overall curve (up or down along the volume axis) to achieve zero volume at large negative pressures, thus achieving the condition of an occluded artery at high cuff pressures. The constraint that the volume cannot be negative is imposed.

An interesting feature of this equation is that it is monotonically increasing, which is a known feature of the arterial pressure-volume curve. In summary, this curve uses parameters which have physiological significance. It is important to note that other general curve equations could be used, but the parameters would probably not have the direct physiological significance and, in some cases, a monitonically increasing constraint would need to be imposed.

Referring to this new reconstruction method, the starting point is the volume oscillations (Vosc), versus cuff pressures as described above and shown in example form in FIGURE 12. The general mathematical form for the pressure-volume curve is assumed and plotted for an arbitrary initial choice of parameters. Given these assumed choices out of a virtual infinity of possible choices, one can simulate mathematically what the volume oscillometric envelope would look like using the same cuff pressures that occurred during the actual determination sequence. The result of this simulation is plotted as Voscsim in FIGURE 12.

The essence of this simulation is that for assumed values of Ao, C, E, SLOPE, and blood pressure, one can estimate the volume oscillations which would be observed by the cuff at different cuff pressures. The estimated values can then be compared with the actual measured values.

The best way to conceptualize this result is to assume a cuff pressure of Pc and that the blood pressure

is instantaneously at Pd, or diastolic pressure. Wall pressure is now at (Pd-Pc), using the sign convention shown in FIGURE 12. Under these conditions, the assumed volume of the artery is determined by Equation 1. The blood pressure now goes from Pd to Ps, or systolic pressure. Wall pressure is now (Ps-Pc) and the assumed arterial volume increases to VARTEST (Pd-Pc). Change in volume is now VOSCSIM=VARTEST(Ps-Pcs) - VARTEST(Pd-Pcd), where Pcs and Pcd are cuff pressures at systolic and diastolic pressures, respectfully. VOSCSIM is calculated for each of the cuff pressure points which occurred in the actual determination process and results in the VOSCSIM variable plotted in FIGURE 12.

The correct choice of unknown parameters is the one which minimizes the error between the measured volume oscillometric waveform and the estimated oscillometric waveform. Individual point by point errors are calculated and then the sum of the errors squared is calculated. FIGURE 13 shows the results of this search optimization process.

There are two additional details. For positive values of E, which has the effect of sliding the assumed pressure-volume curve along the volume axis, there is no effect on the goodness of fit. By introducing a nonlinear constant (volume cannot be negative), negative E values improve the curve fit by sliding the pressure-volume curve along the volume axis. This is conceptually consistent with knowing that the artery is occluded at cuff pressure significantly above systolic pressure. In these examples, the sum of the errors squared between the assumed pressure-volume curve and the measured volume oscillometric curve is calculated for negative wall pressures. This is summed on a weighted basis with the original objective function and forms a new objective function.

The second detail involves the interaction of the calibration method with the pressure-volume curve parameters. When air is expelled from the cuff, during a cuff decrement/calibration step, in other words for a point C, to a point C_2, the unknown pressure-volume curve must also be accounted for in the estimate of expelled air. This is reproduced as Equation 2 below:

EQUATION 2

$$\Delta V_{outcorr} = \Delta V_{out}(\text{ from } P_{c1} \text{ to } P_{c2}) - \Delta V_{art}(\text{from } P_{c1} \text{ to } P_{c2}) \quad (2)$$

where

$\Delta V_{outcorr}$ = Corrected volume change

ΔV_{out}(from P_{c1} to P_{c2}) = Determined from measurements

ΔV_{art}(from P_{c1} to P_{c2}) = $V_{art}(P_{bp}-P_{c2})-V_{art}(P_{bp}-P_{c1})$

For instance, assume that the blood pressure is constant at some pressure X. At cuff pressures significantly above X, the artery is completely collapsed. When air is expelled, the artery volume changes only minutely because of its complete collapse. Under these conditions, the estimate of (ΔVout) used in Equation 2 is appropriate because the arterial volume is not changing significantly during the decrement. The situation is different especially when wall pressure is around zero. Now the artery increases in volume with each decrement. The appropriate estimate of (Δvout) is now (ΔVoutcorr) shown in Equation 2, which holds across all cuff pressures. The overall effect is to modify the ΔVout estimate of Equation 2. This, in turn modifies Voscsim. FIGURE 14 compares the two versions of Voscsim, and FIGURE 15 shows optimization of the corrected Voscsim to the measured Vosc.

Based on the disclosure of this general method which does not have prior knowledge of any of the parameters, it is clear the method can also work if one has prior knowledge of one or both of the blood pressure estimates achieved through separate means.

Systolic and pulse pressures are unknown at this point and they can be albragetically labeled as unknowns S and P. The problem now involves six or five unknown constants, and the inverse problem is a choice of constants which will best match the volume pressure envelope Vosc, as shown in FIGURE 12. Such estimated values A_o, C, E and slope produce a guessed pressure-volume curve as shown as Voscsim in FIGURE 12.

One solution to this problem is to assume diastolic and systolic pressure values, these are initially chosen at 120mm Hg and 40mm Hg, because they are the normal values of the whole population. Given these assumed choices one out of a virtual infinity of possible choices, one can simulate mathematically what the volume oscillometric envelope would look like using the same cuff pressures that occur during an actual determination sequence.

As seen in FIGURE 14, there is described an improved sequence for resolving the equation. This method now determines the parameters using initial assumed values of A_o, C, E, Slope, S and P. This method therefore, estimates the volume change observed at various cuff pressures. The best way to conceptualize this theory is to assume a cuff pressure of Pc, so that blood pressure is instantaneously shown as S. Wall pressure at this given Pc is now determined as S-Pc. Under these conditions, the assumed volume of the artery is known and can be plotted against wall pressure as in FIGURE 14. The blood pressure now varies from S to S-P. Wall pres-

sure also varies from (S-P) to (S-P-Pc), and the assumed arterial volume decreases accordingly.

Thus, an assumed shape of the pressure curved affects both the dV/P estimate obtained during the calibration decrement, as well as the shape in which the simulated volume oscillometric curve takes. A best choice of parameters is still the set which minimizes the error between the volume of the curved obtained from this determination. What these determinations result in are actual measurements of all the parameters, including diastolic and systolic pressures, as compared to previous methods which only determine parameters on a scaled basis. In other words, there is no scaling of any of the parameters values, and actual numbers can be obtained. This will allow the user to obtain much more robust meanings for these readings and, therefore, allows for immediate and applicable in using these known methods.

It is, therefore, meant that the following claims and their equivalents cover the scope of the invention as previously described.

Claims

1. Instrumentation for performing measurements of the vital signs comprising:
an inflatable cuff;
means, connected to said cuff for inflating and deflating said cuff;
means for detecting pressure levels of said cuff;
means for removing quantified decrements of air from said cuff;
means for computing values of oscillation volume from said quantified decrements of air; and
means for computing arterial volume as a function of said values of said oscillation volume and cuff pressure, wherein said computing means comprise means for estimating said arterial volume and creating a volume versus pressure curve.

2. Instrumentation according to Claim 1, wherein said computing means computes arterial volume as a function of said values of oscillation volume and cuff pressure.

3. Instrumentation according to Claim 1, wherein said computing means computes arterial volume as a function of transmural pressure.

4. Instrumentation according to Claim 1 wherein said computing means computes systolic and diastolic pressure as a function of arterial volume.

5. Instrumentation for performing measurements of vital signs comprising:
an inflatable cuff;
means for inflating said cuff;
means for detecting pressure levels within said cuff;
means for expelling air from said cuff; and
computing means capable of computing arterial volume as a function of said air expelled from said cuff and said detected pressure levels, wherein said computing means is also capable of computing systolic and pulse pressures using said computed arterial volume.

6. Instrumentation according to Claim 5, wherein said expelling means comprises an orifice of known flow characteristics.

7. Instrumentation according to Claim 5, wherein said expelling means comprises a volume of known characteristics which is selectively coupled to said cuff.

8. Instrumentation according to Claim 7, wherein said air expelling means includes a deflate valve for expelling air from said cuff through said orifice; and wherein said computing means includes:
means for computing flow through said orifice as a function of cuff pressure;
means for computing the volume flow of air expelled as a function of flow, orifice characteristics, and the time said deflate valve is open; and
means for computing arterial volume as a function of said volume of air expelled and cuff pressure.

9. Instrumentation for performing measurements of vital signs comprising:
an inflatable cuff;
means for inflating said cuff;

means for detecting pressure levels within said cuff;
means for expelling air from said cuff; and
computing means capable of computing arterial volume as a function of said air expelled from said cuff and said detected pressure levels, wherein said computing means is also capable of creating a volume versus pressure curve.

10. The instrumentation of claim 9 wherein said computing means is also capable of computing systolic and pulse pressures using said computed arterial volume.

11. Instrumentation for performing measurements of arterial volume comprising:
an inflatable cuff;
means, connected to said cuff, for inflating and deflating said cuff;
means for detecting pressure levels within said cuff;
means for computing arterial volume as a function of said detected pressure levels within said cuff;
means for computing arterial capacity as a function of pressure; and
further including means for computing systolic and pulse pressures as a function of said arterial volume and computed pressure levels.

12. Instrumentation according to Claim 11, including displaying means which displays systolic and pulse pressures.

13. A method of determining arterial capacity comprising the steps of:
inflating a cuff around a peripheral part of the body;
incrementally deflating said cuff;
detecting the pressure within said cuff during said deflating of said cuff;
determining incremental quantities of air removed from said cuff during the deflating of said cuff; and
using said incremental quantities of air to compute arterial volume, systolic pressure and pulse pressure.

14. The method of Claim 13, wherein said determining step comprises measuring the flow of air through an orifice of known characteristics.

15. The method of Claim 13, wherein said determining step comprises measuring the volume of air transferred from said cuff to a volume of known characteristics.

16. The method of Claim 13, further comprising the step of calculating the arterial volume of said peripheral body part as a function of cuff pressure.

17. The method of Claim 13, further comprising the step of calculating the arterial volume of said peripheral body part as a function of transmural pressure.

18. The method of Claim 13, wherein said calculating step comprises the step of calculating the arterial volume of said peripheral body part as a function of systolic pressure.

19. The method of Claim 18 further comprising the step of calculating systolic pressure as a function of arterial capacity.

20. The method of Claim 13, further comprising the step of calculating oscillation volume as a function of the incremental quantities of air removed from said cuff and detected pressures within said cuff.

FIG. 1

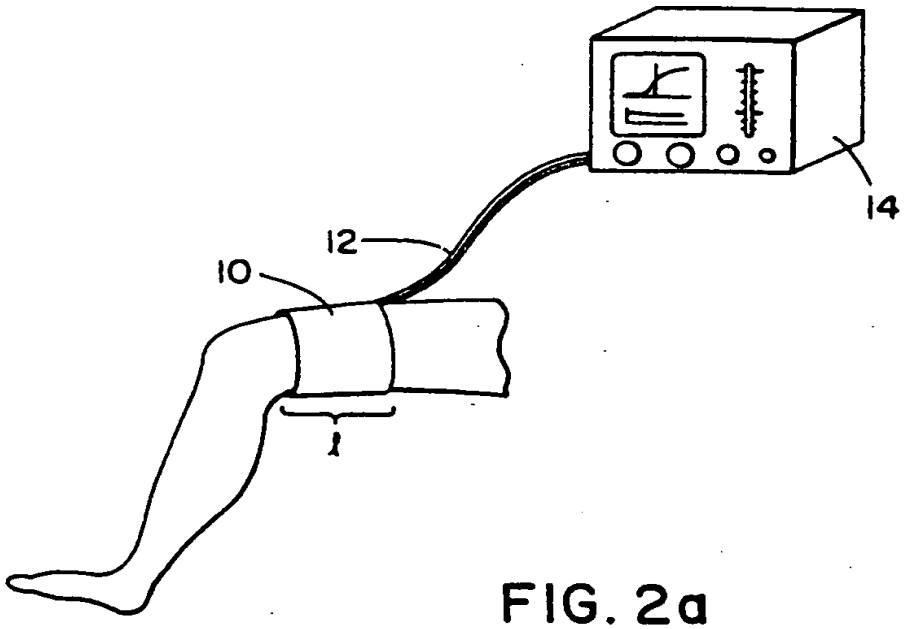

14
12
10
l

FIG. 2a

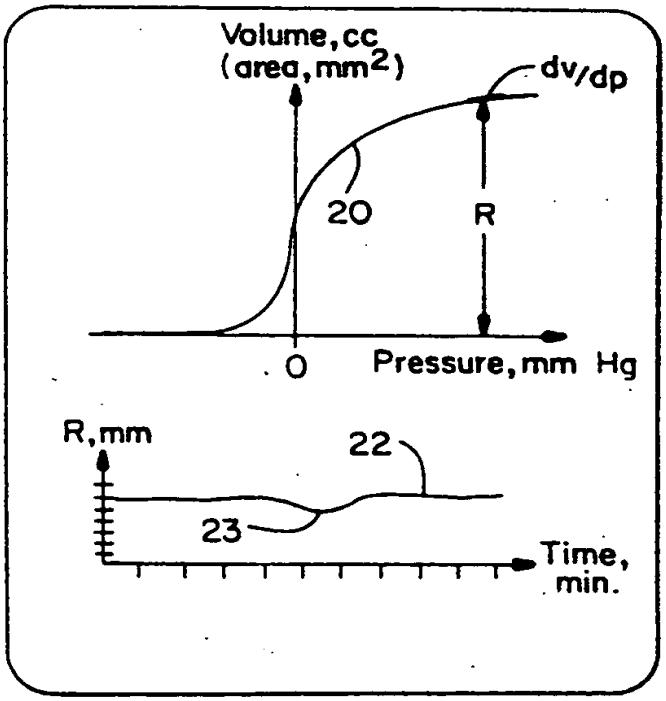

Volume, cc
(area, mm2)
dv/dp
20
R
0
Pressure, mm Hg
R, mm
22
23
Time,
min.

FIG. 2b

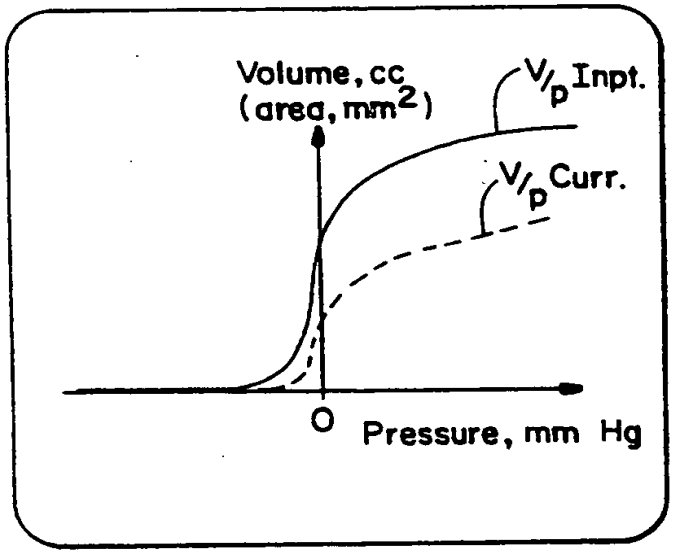


FIG. 3a

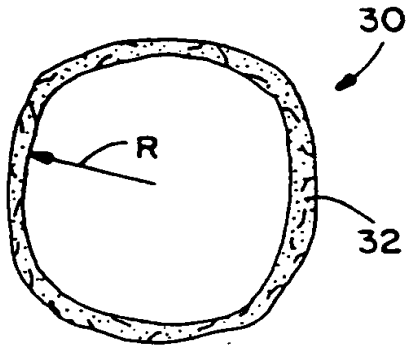


FIG. 3b

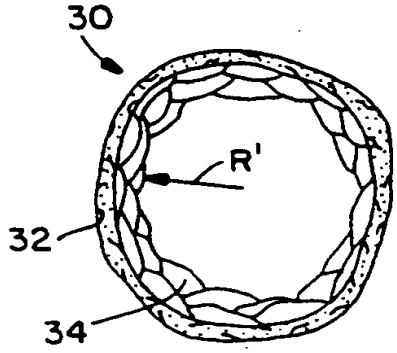


FIG. 4

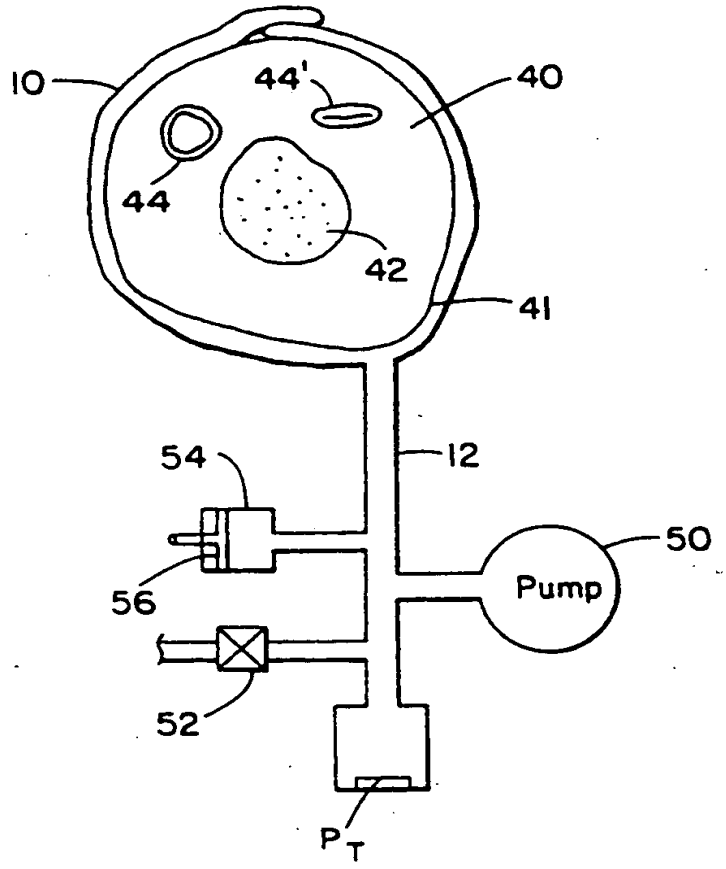


FIG. 5

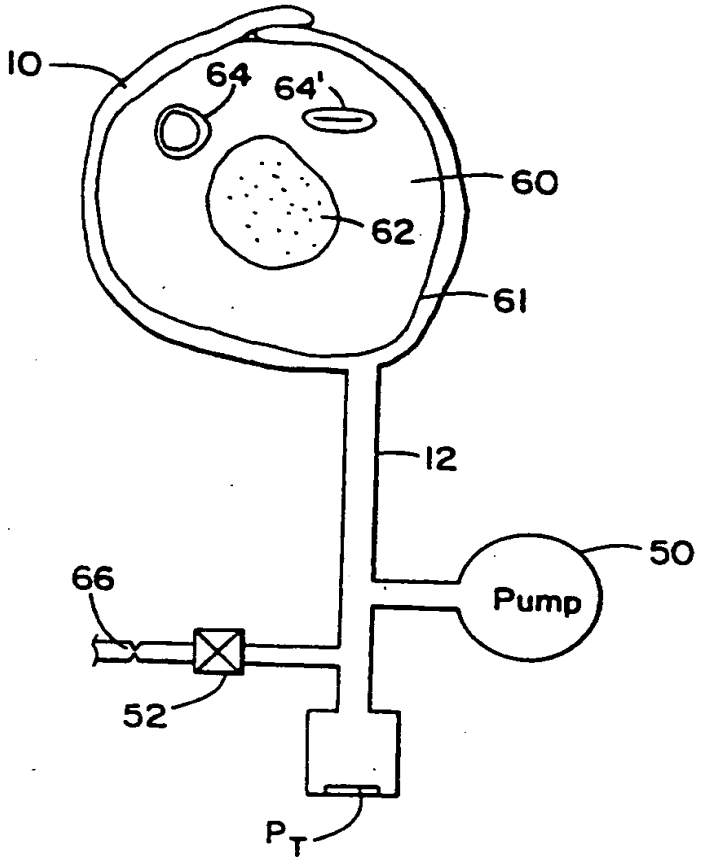

10
64
64'
60
62
61
12
50
Pump
66
52
P_T

FIG. 6

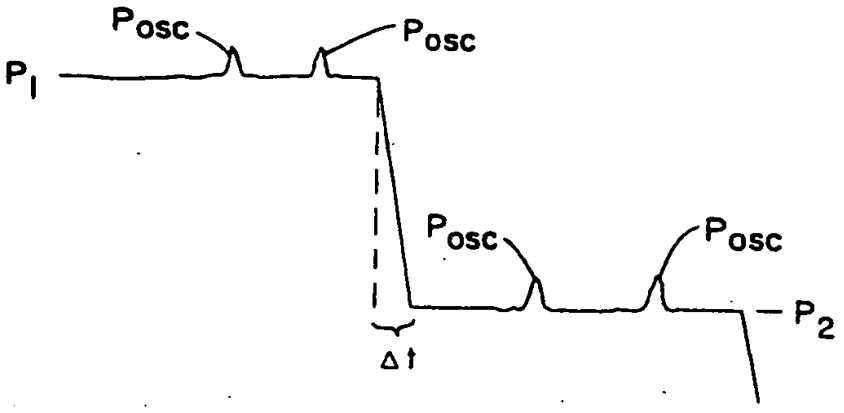

P_{osc}
P_{osc}
P_1
P_{osc}
P_{osc}
P_2
Δt

FIG. 7

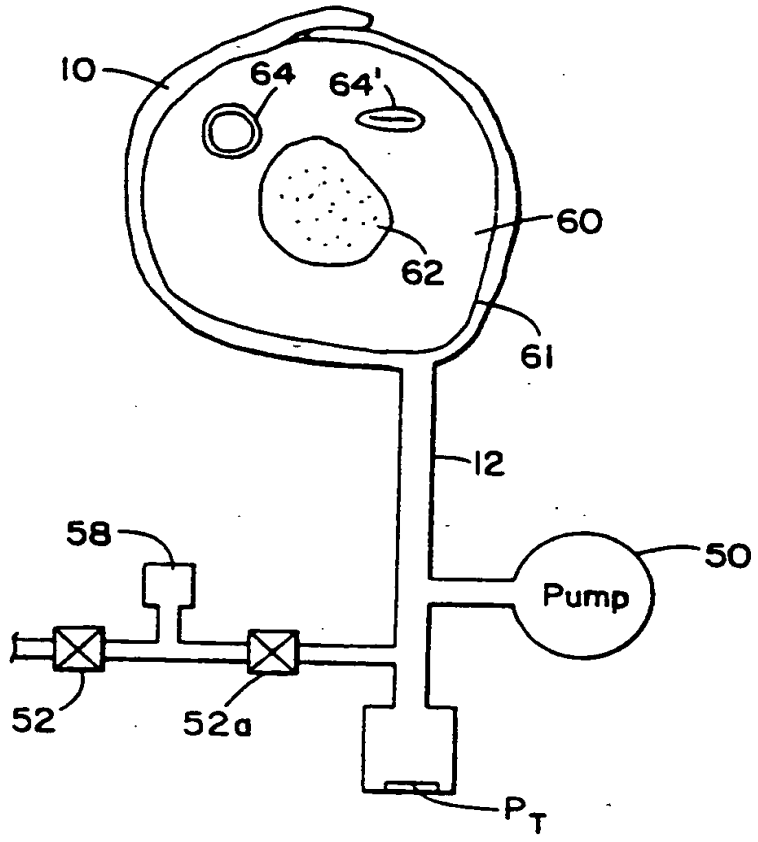

10
64
64'
60
62
61
12
58
50
Pump
52
52a
P_T

FIG. 8

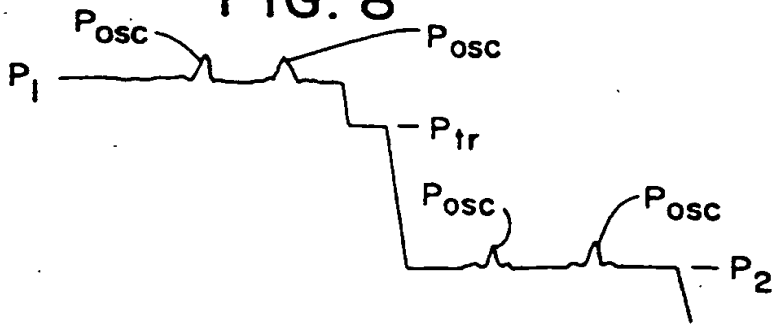

P_{osc}
P_{osc}
P_1
P_{tr}
P_{osc}
P_{osc}
P_2

FIG. 10

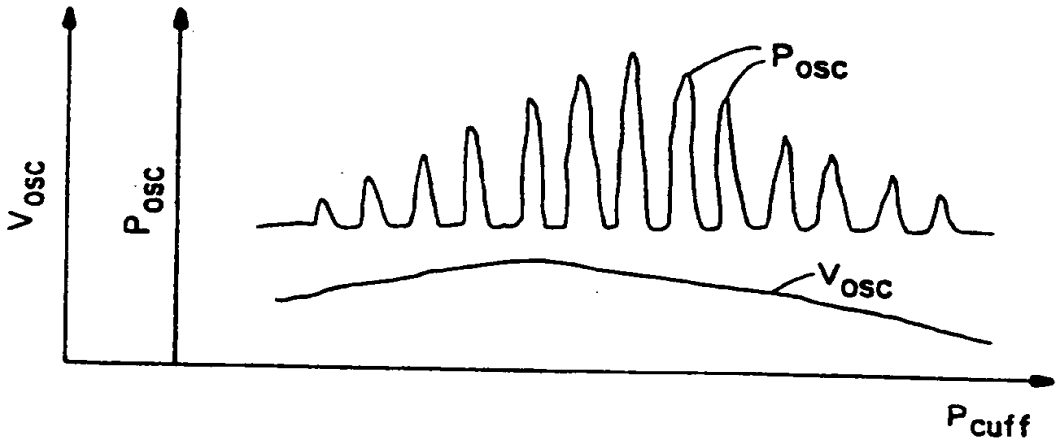

V_{osc}
P_{osc}
P_{osc}
V_{osc}
P_{cuff}

FIG. 9

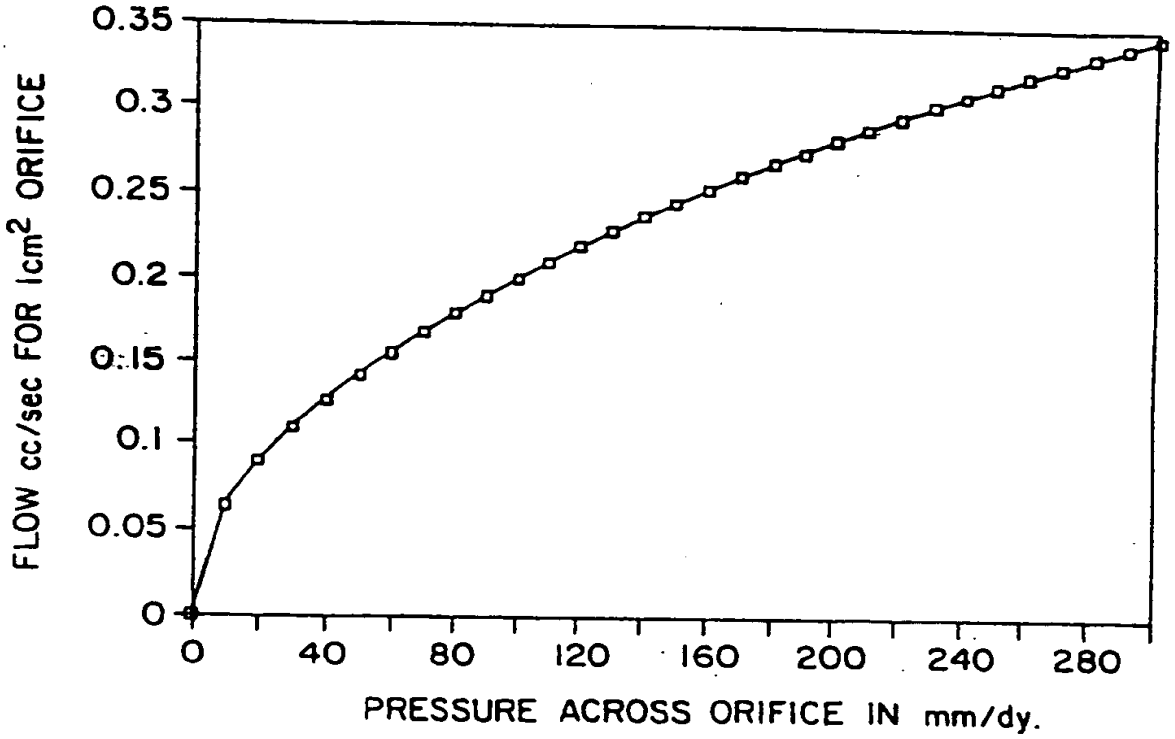

FLOW cc/sec FOR 1cm² ORIFICE
0.35
0.3
0.25
0.2
0.15
0.1
0.05
0
0
40
80
120
160
200
240
280
PRESSURE ACROSS ORIFICE IN mm/dy.

FIG. 11

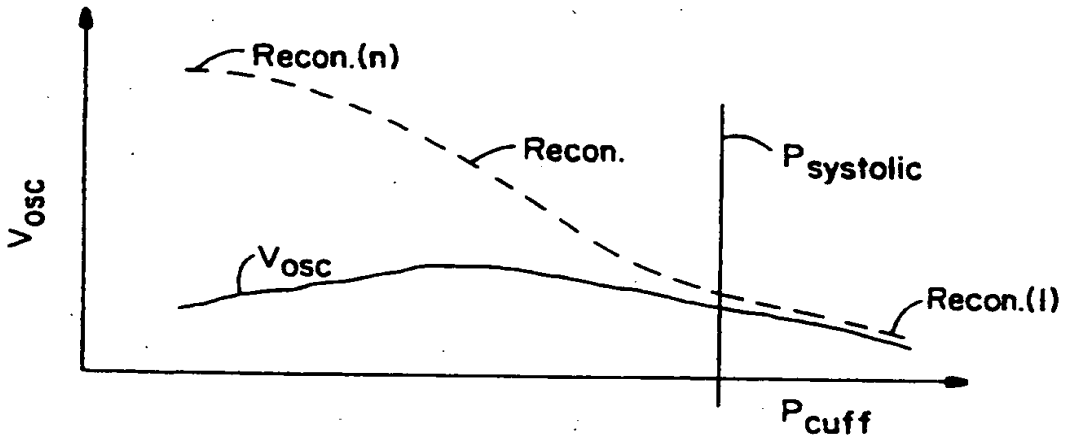


FIG. 12

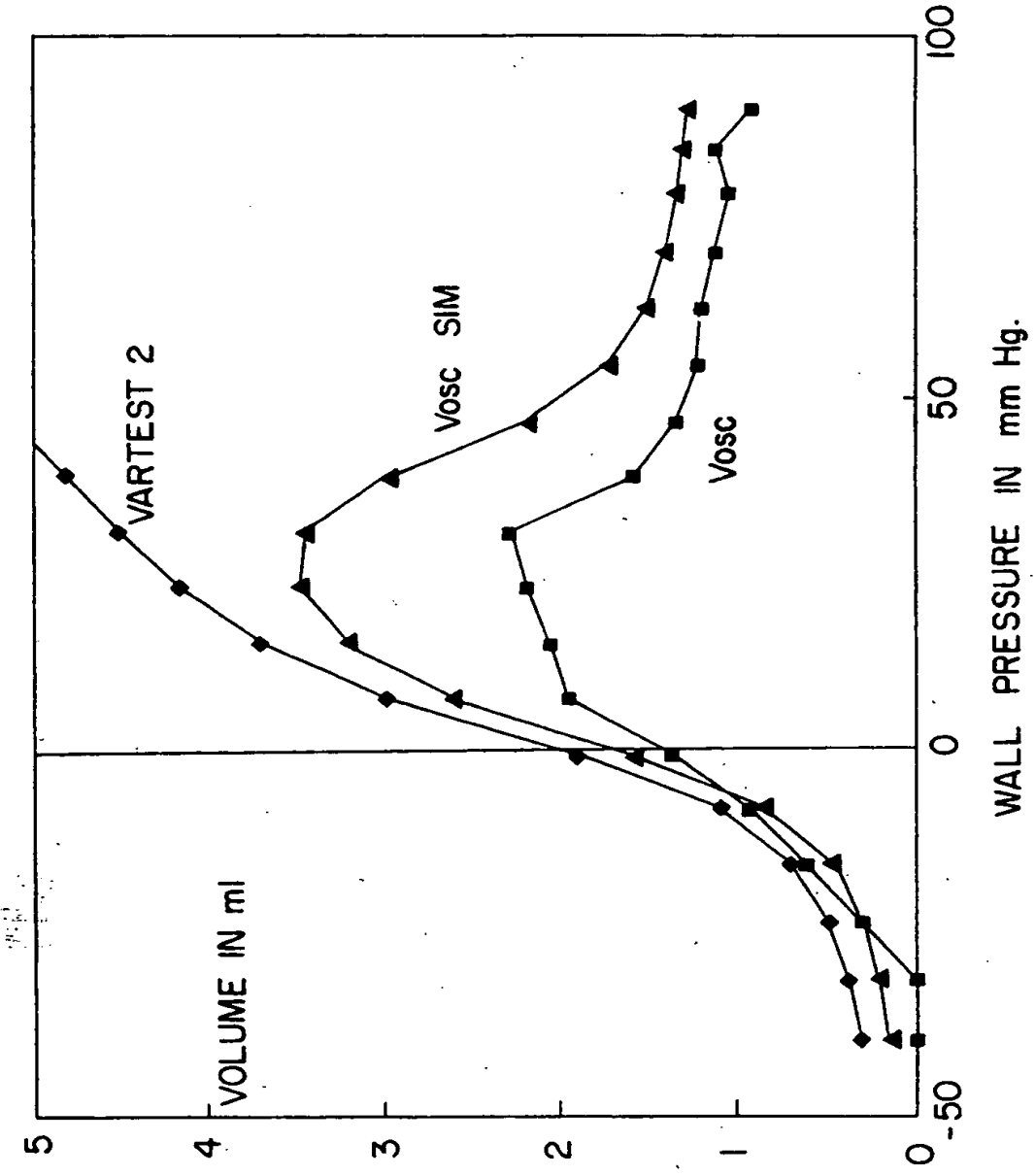

VARTEST 2
Vosc SIM
Vosc
VOLUME IN ml
WALL PRESSURE IN mm Hg.
0
1
2
3
4
5
-50
0
50
100

FIG. 13

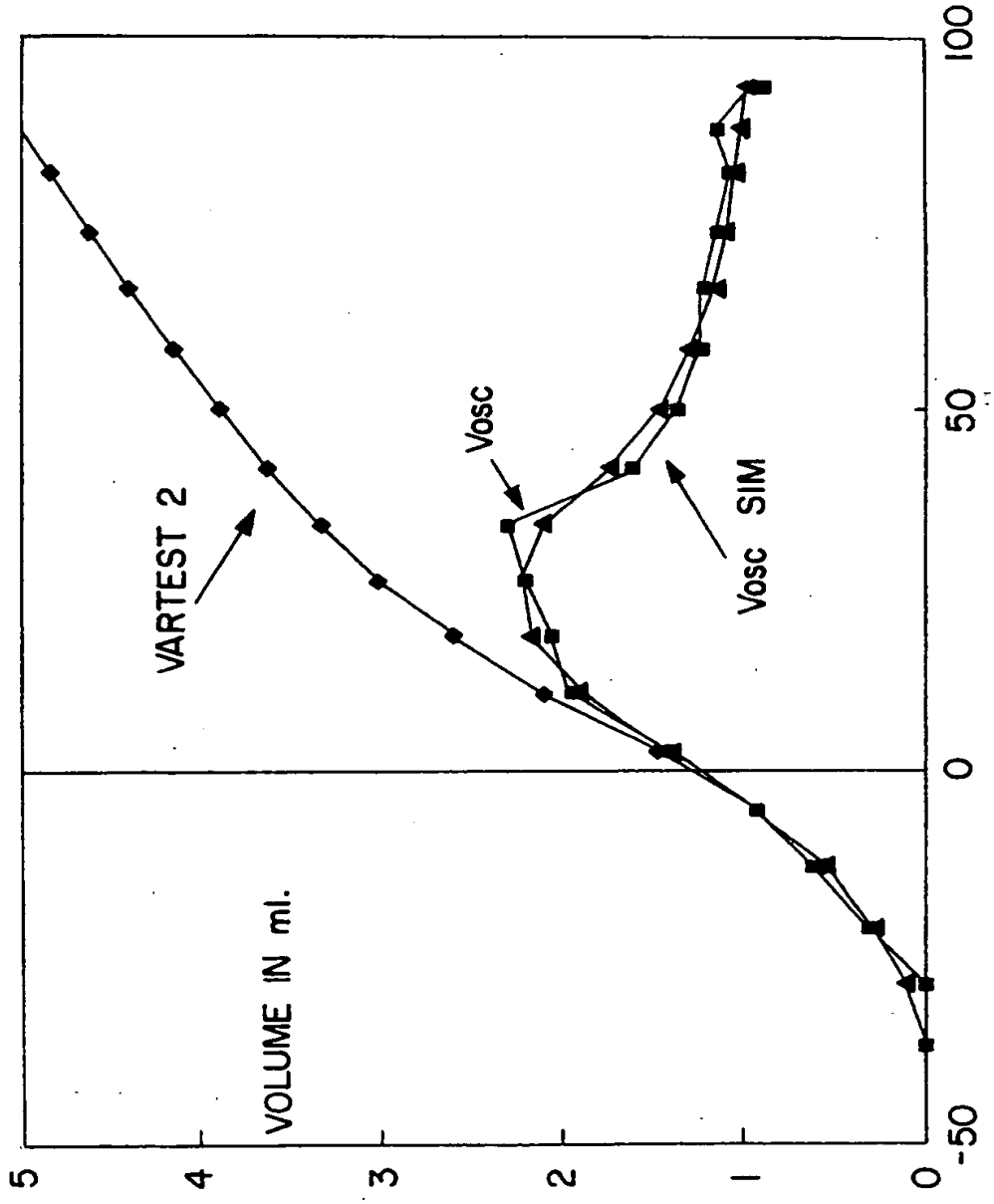


FIG.14

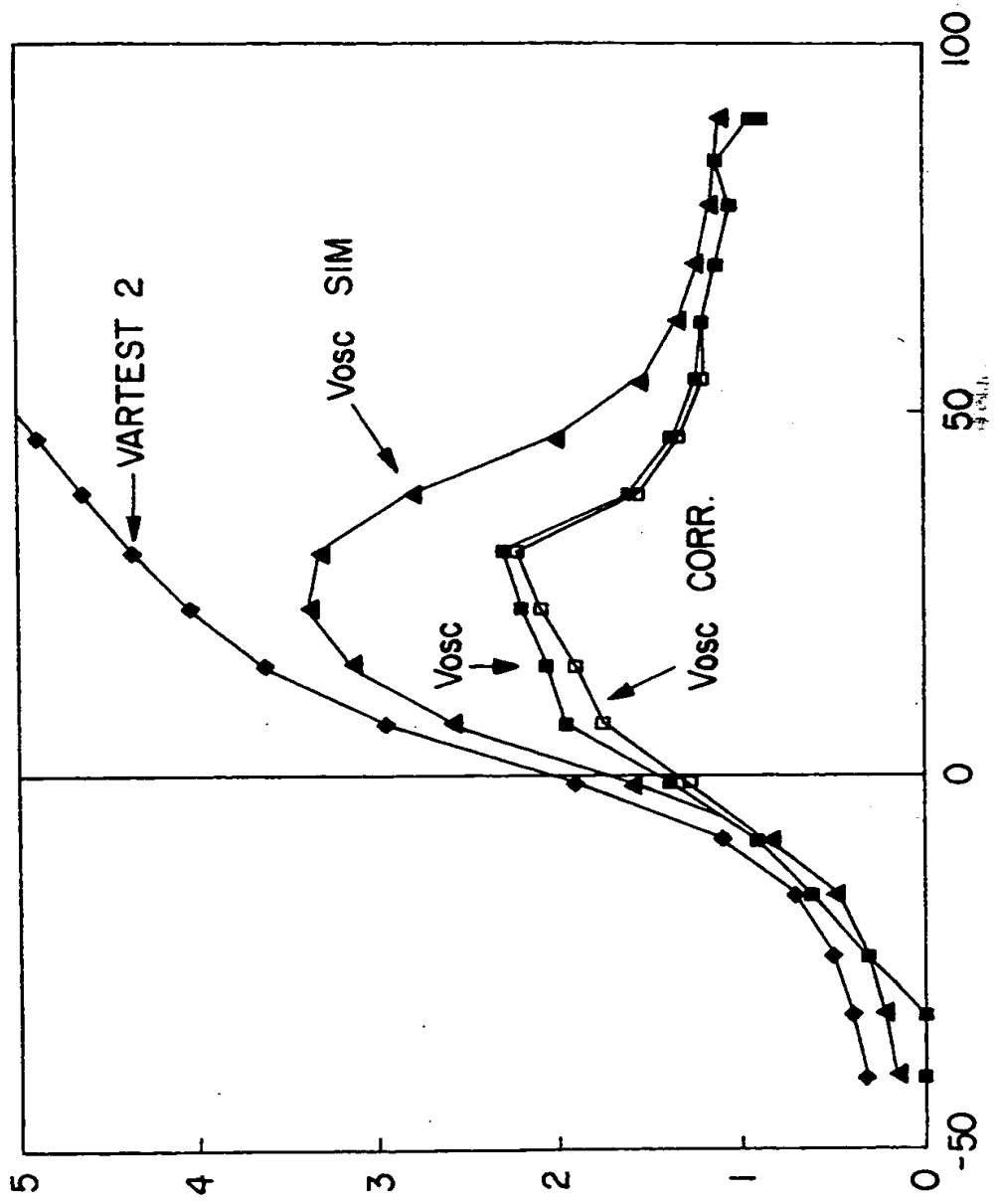
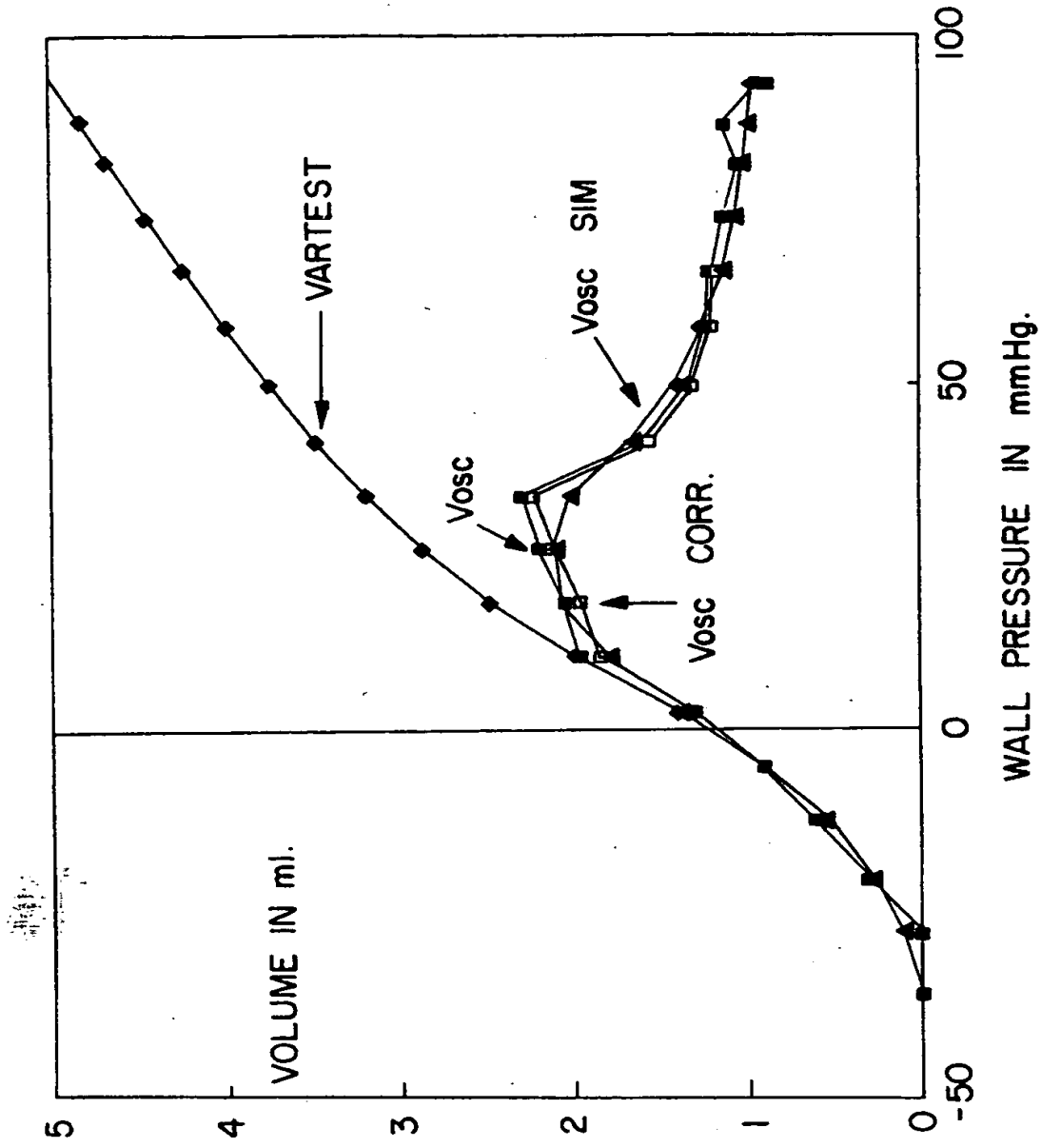


FIG. 15


VARTEST
Vosc SIM
Vosc
Vosc CORR.
VOLUME IN ml.
WALL PRESSURE IN mmHg.
5
4
3
2
1
0
-50
0
50
100

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 94 30 3197

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.5)
X	WO-A-92 22239 (FLORIDA ATLANTIC UNIVERSITY RESEARCH CORP.)	1-3,5,7, 9,15-17	A61B5/022
X	* page 30, line 6 - line 31 *	19,20	
A	* page 38, line 22 - page 40, line 17 * * page 43, line 5 - page 47, line 19 * * page 49, line 13 - page 52, line 29 *	11	
X	EP-A-0 434 399 (CRITIKON, INC.)	1-3,7,9	
X	* page 4, line 27 - page 5, line 58 *	15-17,20	
A	* page 6, line 51 - page 7, line 43 *	5,11,13	
D,X	& US-A-5 103 833 (H.P. APPLE)	1-3,7,9, 15-17,20	
X	EP-A-0 188 894 (AMERICAN HOSPITAL SUPPLY CORP.)	1-5, 9-13,16	
D,X	& US-A-4 699 152 (W.T. LINK)	1-5, 9-13,16, 17	
X	* page 3, line 8 - page 9, line 9 * * page 39, line 5 - page 47, line 35 *	17	
A	CH-A-515 028 (ORIPID A.G.)	1-5,7	TECHNICAL FIELDS SEARCHED (Int.Cl.5)
A	* column 5, line 61 - column 6, line 63 *	9-13,15	A61B
A	* column 9, line 12 - column 10, line 7 * * column 11, line 12 - column 13, line 14 *	20	
D,A	US-A-4 712 563 (W.T.LINK)	1,2,4,5	
A	* column 2, line 19 - line 65 * * column 5, line 3 - column 6, line 53 *	11-13,17	
A	US-A-3 920 004 (R. NAKAYAMA)	1-5	
A	* column 3, line 31 - column 4, line 63 * * column 7, line 63 - column 9, line 12 *	11-13	

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	1 September 1994	Rieb, K.D.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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E : earlier patent document, but published on, or after the filing date
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L : document cited for other reasons

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